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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,956	03/26/2004	John C. Bischof	110.02150101	9825

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EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,956	<b>Applicant(s)</b> BISCHOF ET AL.	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/9/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed on February 9, 2006, with respect to the rejections of claims 1-6 under 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (U.S. Pat. No. 6,231,536 B1) in view of Falk (Falk MH, Issels RD.

Hyperthermia in oncology. *International Journal of Hyperthermia* 2001; 17(1):1-18).

Regarding claim 1, Lentz discloses a method of performing a thermal surgical procedure, comprising:

contacting biological material with an inflammation inducing composition, wherein inflammation is induced in at least a portion of the biological material (col. 2, ln. 26-33).

The claim differs from Lentz in calling for identifying biological material to undergo the thermal surgical procedure and adjusting the temperature of the identified biological material, wherein at least a portion of the biological material is destroyed after undergoing the thermal surgical procedure. Lentz discloses treating the biological material with radiation doses that generate carbonium ions (col. 7, ln. 32-34 and col. 7, ln. 39-40).

Falk, however, teaches combining ionizing radiation that is administered in doses with hyperthermia to further augment tumor destruction (Abstract and Section 2.1, pg. 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used hyperthermia in combination with the radiation treatment of Lentz in view of the teaching of Falk in order to further augment tumor destruction. Identifying biological material to undergo the thermal surgical procedure is a step that inherently occurs before treating a desired region of tissue.

Regarding claim 3, Lentz discloses the method claim 1 in view of Falk. In addition, Falk discloses adjusting the temperature to comprise raising the temperature above a physiological temperature of the biological material (Abstract).

Regarding claim 4, Lentz discloses the method of claim 1 in view of Falk. In addition, Lentz discloses that the biological material is selected from the group consisting of cells, tissues, and combinations thereof (col. 1, ln. 63-64).

Regarding claim 5, Lentz discloses the method of claims 1 and 4 in view of Falk. In addition, Lentz discloses that the cells are tumor cells (col. 1, ln. 63-64).

Regarding claim 6, Lentz discloses the method of claims 1 and 4 in view of Falk. In addition, Lentz discloses that the tissues are selected from the group consisting of tumor tissues, liver tissue, prostate tissue, breast tissue, kidney tissue, vascular tissue, gastrointestinal tissue, muscle tissue, skin tissue, connective tissues, and combinations thereof (col. 1, ln. 63-64 and col. 5, ln. 29-32).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz ('536) in view of Falk and further in view of Pettus (U.S. Pat. No. 5,722,985).

Regarding claim 2, Lentz discloses the method of claim 1 in view of Falk. The claim differs in calling for adjusting the temperature to comprise lowering the temperature below a physiological temperature of the biological material. Pettus, however, teaches using radiation in combination with either hyperthermia therapy or cryotherapy to treat a tumor (col. 3, ln. 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Lentz in view of Falk to include cryotherapy instead of hyperthermia as an

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obvious alternate supplementary treatment that is well-known in the art for treating tumors.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4441486 A	USPAT	Pounds; Douglas W.
US 4528979 A	USPAT	Marchenko; Alexandr T. et al.
US 4872458 A	USPAT	Kanehira; Katsuyuki et al.
US 4920978 A	USPAT	Colvin; David P.
US 5067952 A	USPAT	Gudov; Vasily F. et al.
US 5425940 A	USPAT	Zimmerman; Robert et al.
US 5620479 A	USPAT	Diederich; Chris J.
US 5714170 A	USPAT	Baserga; Renato et al.
US 5902582 A	USPAT	Hung; David T.
US 6146897 A	USPAT	Cohenford; Menashi A. et al.
US 6190378 B1	USPAT	Jarvinen; Philip O.
US 6305380 B1	USPAT	Hellstrand; Kristoffer et al.
US 6451044 B1	USPAT	Naghavi; Morteza et al.
US 6749624 B2	USPAT	Knowlton; Edward W.
US 6772766 B2	USPAT	Gallo; Richard et al.
US 6805701 B1	USPAT	Cortes; Marta

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT *AK*  
3/23/06

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER